collaborates with NCHSTP investigators to conduct HIV epidemiologic and surveillance studies worldwide particularly as they pertain to prevention and intervention strategies; (3) identifies and characterizes new HIV isolates and develops new screening tests for these isolates to determine their prevalence in various populations; (4) determines geotypic and phenotypic variations of HIVs that may affect pathogenesis, drug resistance, persistence, virulence, and transmissibility; (5) conducts and supports field epidemiologic investigations of the prevalence, distribution, trends, and risk factors associated with non-AIDS retroviral infections and associated diseases; (6) serves as a World Health Organization (WHO) Reference Center and as a member of the UNAIDS Virus Network to provide international consultation and technical assistance on laboratory procedures for HIV isolation, detection, and characterization; (7) develops and evaluates procedures for the isolation and characterization of HIV and for the detection of retroviral DNA or RNA from clinical samples; (8) provides training, reference testing, and reference reagents for virologic and molecular characterization of divergent HIVs for public health laboratories in the United States and WHO; (9) serves as a reference laboratory for the isolation of zoonotic retroviruses from clinical samples; (10) develops collaborations with other CDC and non-CDC scientists to promote scientific progress and accomplishments; and (11) collaborates with industry to promote commercialization of useful technology, methodologies, and reagents of public health importance.

HIV Immunology and Diagnostic Laboratory Branch (HCK58). (1) Conducts basic and applied studies of microbial-host interactions that occur in infections, particularly infection with human immunodeficiency virus (HIV); (2) conducts basic and applied investigations of the immune cell interactions that occur in HIV infection as well as in related immunologic/infectious diseases; conducts investigations of genetic traits of the host that influence the susceptibility, disease course, and immune response to infectious disease, particularly HIV diseases; (3) conducts studies related to the development, evaluation, improvement, and standardization of laboratory technologies uses for the diagnosis, surveillance, and monitoring of HIV infection both independently and in collaboration with the biotechnology industry; (4) performs HIV antigen and antibody testing plus related standardized assays in support of the diagnostic/surveillance/epidemiologic requirements of CDC-based and CDC-affiliated studies of the HIV epidemic; (5) serves as a reference laboratory for State and local health departments; and (6) provides diagnostic services to other Federal agencies, the World Health Organization, CDC-affiliated academic centers, CDC-affiliated studies with other countries, and community organizations, as appropriate.

Dated: April 1, 2005.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 05–21672 Filed 10–31–05; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Notice of Grant Award to MedCO Health Solutions, Inc., To Evaluate an Open-Source Project Entitled, ''A Comparison of Multiple Methods to Incent Physicians To Adopt Electronic Prescribing Devices''

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Notice of Grant Award.

SUMMARY: The Centers for Medicare and Medicaid Services has awarded a grant entitled, ''A Comparison of Multiple Methods To Incent Physicians To Adopt Electronic Prescribing Devices'' to Medco Health Solutions, Inc., 100 Parsons Pond Drive, Franklin Lakes, NJ 07417 in response to an unsolicited proposal. The period of performance is August 1, 2005 through July 31, 2006. The purpose of this grant is to fund an initial evaluation of the Southeastern Michigan e-Prescribing Initiative (SEMI) project. Through the use of e-prescribing, this program is intended to reduce the costs associated with the use of prescription drugs, and improve safety for patients, including Medicare beneficiaries, associated with an estimated 6,000 targeted physicians/prescribers in Southeastern Michigan. The project involves the active collaboration of multiple employers, insurance entities and care providers in eight counties in Southeastern Michigan. Partners include the Big Three automakers, Ford, General Motors and Daimler Chrysler; Blue Cross/Blue Shield of Michigan; Henry Ford Health System/Health Alliance Plan; Health Plus of Michigan; SureScripts, RxHub and MedCo. This is a unique project in terms of size, sponsoring organizations, patient base, geographic area, and approach. This project is consistent with CMS' goals to improve health care quality, patient safety, and the use of electronic prescribing. Funding of this unsolicited proposal will result in a desirable public benefit in that its aim is to provide needed information on the costs and critical success factors associated with the adoption of electronic prescribing, as well as to provide improvements in quality and safety of care delivery.

FOR FURTHER INFORMATION CONTACT: Maria Friedman, Project Officer, Office of e-health Standards and Services, Centers for Medicare and Medicaid Services, 7500 Security Blvd., Stop S2–27–17, Baltimore, MD 21244, (410) 786–6333 or Judy Norris, Grants Officer, Department of Health and Human Services, OOM/AGG/CMS, 7500 Security Blvd., Stop S2–21–15, Baltimore, MD 21244, (410) 786–5130.

Authority: Catalog of Federal Domestic Assistance Program No. 93–779, Center for Medicare and Medicaid Services, Research, Demonstrations and Evaluations; Section 1110 of the Social Security Act.

Dated: August 9, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 05–21731 Filed 10–31–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: The National Evaluation of the Court Improvement Program.

OMB No.: New Collection.

Description: The National Evaluation of the Court Improvement Program will describe the many paths followed by state courts to improve their oversight of child welfare cases, and will provide the field with information on effective models for juvenile and family court reform. Funded by the Children's Bureau, U.S. Department of Health and Human Services (HHS) in 2004, the five-year study is being carried out by a partnership of three organizations consisting of Planning and Learning Technologies (Pal-Tech, Inc.), the Urban Institute and the Center for Policy Research.

The Federal Court Improvement Program (CIP) was established in 1994 as a source of funding for state courts to assess and improve their handling of foster care and adoption proceedings. The funding is codified in title IV–B, subpart 2 of the Social Security Act, Section 438, as part of the Promoting Safe and Stable Families Program. Although anecdotal information documents the program's success, this is the first national evaluation of CIP. This study builds on the recommendations of a Children's Bureau funded evaluability assessment (EA) of the program completed in 2003 by James Bell Associates, Inc.

The National Evaluation of the Court Improvement Program involves three interrelated components:

1. *Reviewing and synthesizing state and local court reform activities:* This component will describe the full range of CIP-funded court reforms undertaken by states at the beginning and ending of the study's data collection period. Additionally, it will provide insights into states' reform priorities and how these shift over time. Especially promising models of reform will be highlighted. Finally, this component will provide important contextual information for the study's in-depth evaluation component of select models of reform. Information for this activity will be synthesized from existing reports submitted by states to the Children's Bureau.

2. *Reviewing and synthesizing existing court reform evaluations:* This component will identify and synthesize findings from research and evaluation conducted on family and juvenile court reforms. It will provide important context for the study's in-depth evaluation component in two ways. Findings on reform activities beyond those captured within the study sites will be provided. It will also help inform evaluation within the study sites by providing information on previously conducted evaluation of similar reform models. Information for this activity will be synthesized from existing evaluations and studies of court reform. Evaluations will be prioritized for synthesis based on their methodological rigor and findings reported in the substantive areas defined by the EA. These are:

- Alternative dispute resolution.
- Training and educational materials.
- Case tracking and management.
- Improvements to the consistency and quality of hearings.
- Parent/caregiver outreach, education, and support.
- Systemic court reforms.

3. *Conducting in-depth studies of reform models:* In-depth evaluation of select models of reform will be undertaken within three, diverse sites across the country. The study designs vary among sites, and include quasi-experimental and descriptive outcome methodologies. Reflecting the Adoption and Safe Families Act, the primary outcome areas of interest will be child safety, the timely achievement of permanency, and child well-being. Within each site, outcome evaluation will be complemented by a qualitative study of the many factors that impacted reform including other related reform efforts, the evolution of the target reform over time, barriers encountered, and methods by which these barriers were overcome.

The outcome evaluation will utilize information from existing court and child welfare agency management information systems. Within select sites, information from these sources will be supplemented with information abstracted from existing court and/or child welfare agency case records. The process evaluation will help inform outcome findings within the study sites as well as provide important insights for the replication of the model within other sites. It will involve the collection of new information through structured focus groups and interviews with key individuals, as well as court observations of child dependency hearings. This descriptive information will be collected twice during the study.

The three sites selected for in-depth analysis are the following:

- *Connecticut's Case Management Protocol:* Piloted in December 1997, the protocol involves a pre-hearing conference of professionals held early in the dependency court process coupled with expanded parent representation.
- *Delaware's Systemic Reform:* Piloted in 2000, the three primary components of the state's comprehensive reform effort are:
- One judge/one case assignment practice where one judge presides over all legal stages of a dependency case
- Defined sequence of hearings and reviews that significantly increases the number of hearings and oversight role of the courts
- Representation for indigent parents in child welfare proceedings
- *Texas' Cluster Courts:* Piloted in 1997, these courts are located in rural areas of the state. Each court serves a cluster of contiguous counties, and a specially trained judge is appointed to travel to each county within a cluster on a given day to hear that county's child welfare cases. The cluster courts were formed to enable rural counties to meet the state's strict permanency statute guidelines that were enacted January 1, 1998.

Collectively, findings from the three study components will capture the ongoing nationwide process of court reform supported by the Court Improvement Program. A technical work group comprised of leading researchers, judicial and child welfare agency officials and representatives of public interest groups has been assembled to provide input at key points during the study.

Respondents: Study respondents include individuals in the following categories among the three study sites noted above:

- Court Improvement Program (CIP) administrators.
- Judges.
- Attorneys (representing the parent, child, and agency).
- Court Appointed Special Advocates (CASAs) and Guardians Ad Litem (GALs).
- Child welfare agency administrators.
- Regional child welfare directors and supervisors.
- Child welfare agency caseworkers.

Annual Burden Estimates

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CIP Administrators	8	1	2	16
Judges	30	1	1	30
Attorneys (parent and agency)	95	1	2	190
CASAs and GALs	55	1	2	110
Child Welfare Agency Administrators	10	1	1	10
Child Welfare Agency Directors & Supervisors	30	1	2	60

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Child Welfare Agency Workers	120	1	2	240
Total				656

Estimated Total Annual Burden Hours: 656.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. e-mail address: *infocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov*.

Dated: October 28, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–21674 Filed 10–31–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0426]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of Participation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for filing a notice of participation with FDA.

DATES: Submit written or electronic comments on the collection of information by January 3, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191)—Extension

Section 12.45 (21 CFR 12.45) issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation, state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in § 12.85. Or, in the case of a hearing before a Public Board of Inquiry (21 CFR 13.25), concerning disclosure of data and information by participants. In accordance with § 12.45(e) the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The respondents are individuals or households, State or local governments, not for profit institutions, and